

510(k) Summary

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Official Contact: Dr. Yuvi Kahana, CEO
Optoacoustics Ltd.
 17 Hanotea St.
 Mazor 73160, Israel
 Tel: (+972) 3-634-4488
 Fax: (+972) 3-634-9292

Proprietary or Trade Name: MRI Multi-Channel Optical Communication System (MOC)

Common/Usual Name: System, Nuclear Magnetic Resonance Imaging (Accessory)

Classification Name: System, Nuclear Magnetic Resonance Imaging (Accessory)
 Product code – LNH
 21 CFR 892.1000
 Class II

Predicate Devices: fMRI Hardware System, Nuclear Magnetic Resonance Imaging System (NordicNeuroLab AS.) K073099
 Silent Scan, Nuclear Magnetic Resonance Imaging (Avotec Inc) K921891

Device Description:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs. The MRI MOC comprises the following main component devices:

Component	Description
IMROC	IMROC is a two-way optical communication device that enables multi-channel dialogs in real time between the MRI Patient, medical Staff and technologists. Communication transmission is based solely on fiber optic cables. IMROC also enables the Patient to listen to music and/or other audio stimulation (e.g., voice commands from the Scanner computer or personnel) during a Scanning session.
IMROC IR Wireless	IMROC IR Wireless is identical in design and function to the IMROC, except that communication transmission is based on wireless infrared (IR) technology as well as fiber optic cables. There are no active components in this device, there are no patient applied parts.
OptoACTIVE	OptoACTIVE is a real-time active noise-cancelling headset that enables two-way communications with the MRI Patient or with MRI Staff while significantly reducing MRI EPI main gradient noise and providing excellent sound quality. OptoACTIVE also enables the Patient to listen to music and/or other audio stimulation (e.g., voice commands from the Scanner computer or personnel) during a Scanning session.

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Sub-Component Devices

The MRI MOC System devices include the following sub-component devices:

Sub-Component	Description
Optical Headsets	<p>Each Headset includes left-and-right high fidelity optical speakers inside a passive noise-reducing casing, coupled with a dual-channel noise-cancelling optical microphone and enables full duplex communications among Staff and Patient. The Headset is fitted with noise-reducing disposable earpads.</p> <ul style="list-style-type: none"> • <u>IMROC/IMROC IR Wireless</u> • <u>OptoACTIVE</u> – The Headset interfaces directly with the System EOU via fiber optic cable. The Headset is available in an optional Ultra-Slim form factor, designed for use in 32-channel head coils.
Control/Mixing Console	<p>The Control and Mixing Console is operated by the technologist in the Control Room to manage the interactive communications environment (e.g., turning off specific headsets, muting Staff/Patient's speaker, adjusting noise cancelling and noise reduction levels, Patient's music volume, etc.).</p> <p>The Console features an MP4 format player to enable selection of appropriate music for a Patient. In addition, the Console enables direct music input from a compatible external player, brought by a Patient.</p> <p>The Console contains a built-in microphone and speaker for direct communications between the technologist and the medical Staff. The Console contains electronic parts and is attached directly to the EOU via electrical cable.</p>
Electro-Optical Unit (EOU)	<p>The Electro-Optical Unit (EOU) is the main processing unit of the System. It receives inputs from the optical Headsets, performs required optical to electrical signal transduction, noise-cancelling and signal enhancement processing, and redistributes communications to Staff and Patient according to current settings on the Control/Mixing Console.</p>
IR Transceiver Unit	<p><i>(IMROC IR Wireless Component Only)</i> A stationary, wall-mounted unit in the Scanner Room which exchanges wireless infrared (IR) signals with the Optical Headsets of each Staff member. It interfaces with the System EOU via fiber optic cable.</p>
Battery Recharging Unit	<p><i>(IMROC IR Wireless Component Only)</i> A stationary, tabletop unit that is intended to be used in the Control Room, where it is easily accessible to Staff responsible for routine System operation. It recharges batteries that are used in the Personal Control Unit, as required. Multiple batteries can be recharged simultaneously.</p>
Hygienic Pop Screens	<p>Specially-fitted pop-screens can be attached to the microphone on the Optical Headset. The screens are designed to be used once per Scanning session, and are disposable.</p>
Hygienic Earpad Covers	<p>Industry standard disposable earpad covers are mounted on left and right earphones on the Optical Headset and are disposable.</p>

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Indications for Use:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.

Patient Population:

The MOC System is designed and intended for use by Patients undergoing functional, interventional and clinical MRI scans. As described above, the System is also used by Doctors and Technologists in these environments.

Environment of Use:

The MOC System is designed and intended for use only in functional, interventional and clinical MRI environments.

Contraindications:

There are no special precautions, warnings or contraindications for using the MOC System.

Comparison to Predicates and Substantial Equivalence:

The following table provides a comparison of the proposed device to the predicates.

The MRI Multi-Channel Optical Communication (MOC) System is viewed as substantially equivalent to the predicate devices because:

Indications – Equivalent to predicates – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Technology – Equivalent technology and design – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Performance – Equivalent to the predicates – NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891).

Performance Testing –

A comprehensive performance testing and evaluation program was developed in order to verify that the MRI MOC System meets its specifications and does not raise any new safety and effectiveness issues in comparison to the predicate devices. The main parts of the testing program were:

- The Electrical Safety and Electromagnetic compatibility of the MOC were tested by external laboratories and testing results demonstrate that the System is in compliance with the requirements of the IEC 60601-1 (and amendments), and IEC 60601-1-2 standards.
- Comprehensive performance evaluation studies were conducted to ensure that the MOC meets its specifications.

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- Comprehensive clinical performance studies were conducted to ensure that the MOC performs effectively, in full accordance with its indications and intended use.
- Risk analysis activities were conducted in accordance with requirements of ISO 14971 “Medical devices – Application of risk management to medical devices” (2007). As concluded from the Risk Analysis procedure, the potential risks of the MOC have been reduced to pre-determined acceptance criteria and the residual risk deemed acceptable.
- Based on these performance testing results, as well the verification and validation processes and an analysis of the similarities and differences presented above, it can be concluded that the MOC is substantially equivalent to the predicate devices without raising new issues of safety or effectiveness.

Conclusion

The MRI Multi-Channel Optical Communication (MOC) System is substantially equivalent to the predicates NordicNeuroLab fMRI Hardware System (K073099) and Avotec Silent Scan (K921891) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

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Manufacturer	Optoacoustics Ltd	NordicNeuroLab AS	Avotec
Description	MRI Multichannel Optical Communication Systems for MRI (MOC)	fMRI Hardware System, Nuclear Magnetic Resonance Imaging System	Silent Scan – (Hearing Protection and Communication System)
Device Manufacturer	Optoacoustics Ltd.	NordicNeuroLab AS.	Avotec, Inc.
Intended Use	The MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.	The fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR Imaging (fMRI) based on Blood Oxygen Level Dependant (BOLD) contrast.	Silent Scan is a hearing protection and communication system intended to provide two-way audio communications and a music listening experience to patients during MR imaging sessions.
Intended Population	The device is intended for use during the MRI procedures as a communication accessory (Patient, Radiologist, Technologists)	The device is intended for use during the MRI procedures as a communication accessory. (subject in fMRI brain studies, not clinical)	The device is intended for use during the MRI procedures as a communication accessory (Patient, Radiologist, Technologists)
Location of Use	Hospital environment (MRI facilities)	Hospital environment (MRI facilities)	Hospital environment (MRI facilities)
Core Technology	Optical Laser, Optical Transduction (converting light modulation to sound), Diffuse Infrared (IR)	Electrostatic Headphone with Electrical Cable	Pneumatic Audio Transmission with Piezo-Electronics Driver
System Components	Patient Optical Headset Staff Optical Headsets Control/Mixing Console Electro-Optical Unit (EQU) IR Transceiver Wall Units Fiber Optic Cables Battery Recharger	Patient Headset Mixing Console Electronic Amplifier Electrical Cables	Patients Headsets Electronic Communication Console with Microphone Electrical Cabling Plastic Tubing Assembly Stereo Interface Box Alarm System (Rubber Squeeze Bulb)
Mode of Operation	Continuous	Continuous	Continuous
Computer-Based	No	No	No
Single Use	The system is reusable	The system is reusable	The system is reusable
Mode of Patient contact	Headset	Headset	Headset
Anatomical Contact Sites	Head	Head	Head
System Accuracy	N/A	N/A	N/A
Compatibility with MRI system	Yes	Yes	Yes

Appendix B

Statement for the Record, K121239

This 510(k) was reviewed under OIVD's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Optoacoustics Ltd
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

MAY 24 2012

Re: K121239

Trade/Device Name: MRI Multi-Channel Optical Communication System (MOC)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 20, 2012
Received: April 24, 2012

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

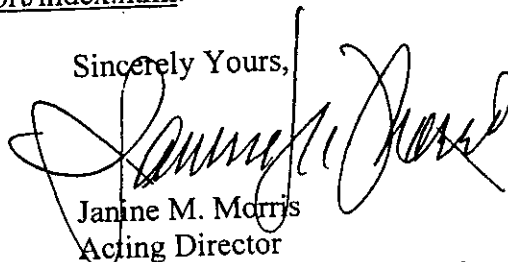
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number

K121239

Device Name

MRI Multi-Channel Optical Communication System (MOC)

Indications for Use:

Optoacoustic's MRI Multi-Channel Optical Communication System (MOC) is intended to facilitate audio communications and stimulation during a scanning session. System devices provide real-time Scanner noise reduction and/or noise cancellation, while enabling multiple concurrent dialogs.

Prescription Use ☒

(Part 21 CFR 801 Subpart D)

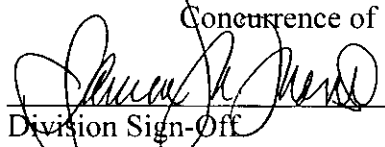
AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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